UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,038	01/09/2004	Avram Reuben Gold	2111-040037	7887

28289 7590 07/07/2009

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/755,038
Filing Date: January 09, 2004
Appellant(s): GOLD, AVRAM REUBEN

Christian E. Schuster
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 7, 2008 appealing from the Office action mailed August 7, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1, 5, 6, 8-12, 16, 17, 19, and 20.

Claims 2-4, 7, 13-15, 18, and 21-28 have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

Claims 1, 5, 6, 11, 12, 16, and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048).

Claims 8, 9, 19, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) in view of Kowallik et al. (6,752,766).

Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) in view of Bennett et al. (5,378,686).

Examiner's Note:

Thornton (5,954,048) was inadvertently misidentified as Threnton (6,769,910) in the last office action.

Kowallik et al. (6,752,766) was inadvertently misidentified as Knowallik et al. (6,752,766).

In section VI of the appeal brief, the appellant stated that only the grounds of rejection to be reviewed on appeal are the rejections of the independent claims (1 and 12) under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048). The dependent claim rejections were also appealed therefore, these claims are included in the new grounds of rejection below.

NEW GROUND(S) OF REJECTION

Claims 1, 5, 6, 11, 12, 16, and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515).

Claims 8, 9, 19, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515) in view of Kowallik et al. (6,752,766).

Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515) in view of Bennett et al. (5,378,686).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,954,048	THORNTON	9-1999
6,752,766	KOWALLIK et al.	6-2004
5,378,686	BENNETT	1-1995
6,322,515	GOOR et al.	11-2001

Declaration of Dr. Mark H. Sanders, filed May 21, 2007.

Examiner's Note:

Appellant inadvertently failed to include a copy of the aforementioned declaration; therefore, Examiner has attached this document to this Examiner's answer.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 6, 11, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515).

As to claim 1, Thornton teaches a method of treating functional somatic syndromes comprising the steps of: determining whether a patent suffers from inspiratory airflow limitation during sleep (the device of Thornton is for treating breathing disorders, i.e. patient suffering from obstructive sleep apnea and snoring, see col.3, lines 10 and 11. Note that the upper airway obstruction is one of the causes of sleep apnea, the disruption of sleep happens because airway muscles tighten, hence creating obstruction of the breathing passage. Thus the device of Thornton is used by patients who are diagnosed with (or "determined to suffer from") inspiratory airflow limitation during sleep; identifying such a patient as having a functional somatic syndrome (Thornton teaches his device is for treating snoring, obstructive sleep apnea, or other breathing disorders, see col. 3, lines 10 and 11). Appellant on page 4 paragraphs [13]-[17] and page 6 paragraph [20] of the specification lists disorders/diseases that are considered functional somatic syndrome. This list includes sleep apnea, snoring, and other breathing disorders (i.e. upper airway resistance syndrome). Thornton teaches a device that is capable of providing treatment for a functional somatic syndrome (combined symptoms of other breathing disorders). In addition, it is known in the art that symptoms are identified by medical personnel to arrive at a

treatment plan to alleviate the patient's medical condition, in order to identify a diagnosis compatible with the symptoms and treatments, thus, upon a physician identifying symptoms associated with a patient suffering from inspiratory airflow limitation during sleep, the physician would treat a patient with the Thornton device, and would utilize the information and knowledge from the symptoms and treatment to arrive at a diagnose of functional somatic syndrome; and treating such a patient with an upper airway stabilization technique (see fig.1a); wherein treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy (see fig.1a, 88). With respect to the steps of determining a patient suffering from inspiratory airflow limitation and identifying a patient having a functional somatic syndrome, Thornton discloses a device for treating sleep apnea. Yet Thornton does not expressly disclose an explicit correlation between the symptoms of functional somatic syndrome and sleep apnea. However, at the time the invention was made, the correlation between the symptoms of functional somatic syndrome and sleep apnea were known. Specifically, Goor teaches sleep apnea is "characterized by repetitive episodes of upper airway collapse during sleeping resulting in interrupted airflow despite persistent respiratory effort." (Column 6, Lines 52-54). Further obstructive apnea is associated with "progressively increasing asphyxia until termination by a brief arousal from sleep and restoration of upper airway patency." (Column 6, Lines 56-57). Thus, this disorder presents a patient having airflow limitation during sleep and would present a person with un-refreshed and fragmented sleep from the repetitive instances of arousal during the sleep cycle. With respect to the determination of a patient suffering from the sleep apnea, Goor teaches diagnosis of the apnea disorder is conducted by the use of a plethora of medical equipment including but not limited to EEG and pulse oximetry. (Column 6, Line 63

thru Column 7, Line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Thornton with a method of treating the functional somatic syndrome as taught by Goor in order to treat the symptoms functional somatic syndrome, such as air flow limitation during sleep.

As to claim 5, Thornton teaches the method as claimed in claim 1, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure (fig.1a, 88).

As to claim 6, Thornton teaches the method as claimed in claim 1, wherein identifying a patient as having a functional somatic syndrome includes identifying a symptom of the functional somatic syndrome, wherein the symptom is selected from the group consisting of: chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, alpha-delta sleep (Thornton teaches a device that can provide treatment of sleep apnea, snoring, and other breathing disorders, see col.3, lines 10 and 11, thus Thornton teaches claimed "muscle pain" and "muscle tenderness" as symptoms of upper airway obstruction syndrome).

As to claim 11, Thornton lacks the method as claimed in claim 1, wherein the functional somatic syndrome is selected from the group consisting of: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple

chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, and restless leg/periodic limb movement syndrome. However, migraine headaches and/or tension headaches can be caused by the obstruction of upper airway muscle. Thus, during the diagnosis of breathing disorders, migraine headaches and /or tension headaches can be documented as symptoms of breathing disorders syndrome. Thus, Thornton's teaching of "other breathing disorders" can include migraine headaches and tension headaches.

As to claim 12, Thornton teaches a method of treating functional somatic syndromes comprising the steps of: determining whether a patient suffers from inspiratory airflow limitation during sleep (the device of Thornton is for treating breathing disorders, i.e. patient suffering from obstructive sleep apnea and snoring, see col.3, lines 10 and 117) Upper airway obstruction is one of the causes of sleep apnea, where disruption of sleep happens because airway muscles tighten, hence creating obstruction of the breathing passage. Thus the device of Thornton is used by patients who are diagnosed with (or "determined to suffer from") inspiratory airflow limitation during sleep; identifying such a patient as having one or more symptom of a functional somatic syndrome (Thornton teaches his device is for treating snoring, obstructive sleep apnea, or other breathing disorders, see col. 3, lines 10 and 11.) Appellant on page 4 paragraphs [13]-[17] and page 6 paragraph [20] of the specification lists disorders/diseases that are considered functional somatic syndrome. This list includes sleep apnea, snoring, and other breathing disorders (i.e. upper airway resistance syndrome) that can be treated by Thornton's device. Thus, Thornton teaches a device that is capable of providing treatment for a functional somatic syndrome (combined symptoms of other breathing disorders). Furthermore, it is known in the art that diagnosis follows treatment, thus, a physician has to identify or diagnose a patent

with functional somatic syndrome prior to prescribing treatment with Thornton's device); and treating such a patient with an airway stabilization technique (via apparatus of fig. 1a); wherein treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy (see fig.1a, 88). Yet Thornton does not expressly disclose an explicit correlation between the symptoms of functional somatic syndrome and sleep apnea. However, at the time the invention was made the correlation between the symptoms of functional somatic syndrome and sleep apnea were known. In addition, Goor teaches sleep apnea is "characterized by repetitive episodes of upper airway collapse during sleeping resulting in interrupted airflow despite persistent respiratory effort." (Column 6, Lines 52-54). Further obstructive apnea is associated with "progressively increasing asphyxia until termination by a brief arousal from sleep and restoration of upper airway patency." (Column 6, Lines 56-57). This disorder presents a patient having airflow limitation during sleep and would present a person with un-refreshed and fragmented sleep from the repetitive instances of arousal during the sleep cycle. With respect to the determination of a patient suffering from the sleep apnea, Goor teaches diagnosis of the apnea disorder is conducted by the use of a plethora of medical equipment including but not limited to EEG and pulse oximetry. (Column 6, Line 63 thru Column 7, Line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Thornton with the treatment method as taught by Goor for treating the symptoms functional somatic syndrome, such as air flow limitation during sleep.

As to claim 16, Thornton teaches the method as claimed in claim 12, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway

pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure (see fig.1a, 88).

As to claim 17, Thornton teaches the method as claimed in claim 12, wherein the symptom of the functional somatic syndrome is selected from the group consisting of: chronic fatigue, irritable bowel, a migraine headache, a tension headache, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, headaches, depression, orthostatic syncope, alpha-delta sleep (Thornton teaches a device that can provide treatment of sleep apnea, snoring, and other breathing disorders, see col.3, lines 10 and 11, thus Thornton teaches claimed "muscle pain" and "muscle tenderness" as symptoms of upper airway obstruction syndrome).

Claims 8, 9, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515), and further in view of Kowallik et al. (6,752,766).

As to claim 8, Thornton/Goor teaches the claimed method step as applied to claim 1. Thornton however lacks the method as claimed in claim 1, further comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient. However, Kowallik teaches claimed step (see col.5, lines 12-20, col.6, lines 10-40, and col.8, lines 7-11) for the purposes of detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col. 3, lines 53-60).

Therefore, it would have been obvious to one of ordinary skill in the art to include means for categorizing patients by type of respiratory disorder as taught by Kowallik. because it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA.

As to claim 9, Kowallik teaches the method as claimed in claim 1, further

comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient (see col.5, lines 12-20 and col.6, lines 10-62).

As to claim 19, Thornton lacks the method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation .of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient. However, Kowallik teaches claimed step (see col.5, lines 12-20, col.6, lines 10-40, and col.8, lines 7-11) for the purposes of detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col. 3, lines 53-60). Therefore, it would have been obvious to one of ordinary skill in the art utilizing Thornton's device with means for categorizing patients by type of respiratory disorder as taught by Kowallik since it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA.

As to claim 20, Kowallik teaches the method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient (see col.5, lines 12-20 and col.6, lines 10-62).

Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Thornton (5,954,048) with extrinsic evidence Goor et al. (6,322,515), and further in view of Bennett et al. (5,378,686).

As to claim 10, Thornton/Goor lacks the method as claimed in Claim 1, further comprising observing alpha-delta sleep of such a patient to diagnose the fictional somatic syndrome. However, Bennett teaches observing alpha-delta sleep of such a patient to aid in diagnosing the functional somatic syndrome. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the modified Thornton's system/method with step of monitoring patients for alpha-delta sleep to diagnose a functional somatic syndrome as taught by Bennett because it would have aided in the diagnosing more serious illness which may also exhibit sleep disorder symptoms.

(10) Response to Argument

Appellant asserts the prior art made of record does not teach or suggest the method of the instant invention would have been obvious, specifically, Appellant asserts the prior art does not teach the relationship between the determining a patient suffering from air flow limitation and the identifying a patient and treating the patient having functional somatic syndrome. Examiner respectfully disagrees.

With respect to the steps of determining a patient suffering from inspiratory airflow limitation and identifying a patient having a functional somatic syndrome, Thornton discloses a device for treating sleep apnea. Regarding the connection between the functional somatic

syndrome symptoms and sleep apnea, extrinsic evidence Goor teaches sleep apnea is "characterized by repetitive episodes of upper airway collapse during sleeping resulting in interrupted airflow despite persistent respiratory effort." (Column 6, Lines 52-54). Further obstructive apnea is associated with "progressively increasing asphyxia until termination by a brief arousal from sleep and restoration of upper airway patency." (Column 6, Lines 56-57). Intrinsically, this disorder presents a patient having airflow limitation during sleep and would present a person with un-refreshed and fragmented sleep from the repetitive instances of arousal during the sleep cycle.

With respect to identifying step, it should be noted Appellant's dependant claim 6, further defines the scope of this method step to include identifying that the patient has a symptom of functional somatic syndrome including un-refreshed sleep, and EEG evidence of sleep fragmentation. Goor teaches diagnosis of the apnea disorder is conducted by the use of a plethora of medical equipment including but not limited to EEG and pulse oximetry. (Column 6, Line 63 thru Column 7, Line 5). As claim 6 is dependant on claim 1 and includes symptoms in a Markush type claim, only one symptom needs to be addressed to meet the claim limitations. In this case, the data from the EEG, used to determine sleep apnea in patients, would enable the health care professional to identify a patient as having functional somatic syndrome symptoms as a result of having a symptom thereof, EEG fragmented sleep.

With respect to the relationship between the determining and identifying, contrary to the statements of Dr. Sanders in his declaration, one of ordinary skill in the art would be motivated to treat functional somatic syndrome symptoms as recited with the device of Thornton in order to improve the respiratory activity of a patient suffering from inspiratory airflow limitation (such as

apnea), as taught by Thornton's abstract, which was determined and identified by the use of EEG and pulse oximetry, as taught by Goor.

With respect to the evidence listed in the evidence appendix, it should be noted that Examiner has provided these documents as filed for the Appellant.

With respect to the other claims pending in this application, claims 5, 6, 8-11, 16, 17, 19, and 20, it should be noted that Appellant has failed to provide arguments for all of the pending claims. Thus, the Examiner respectfully requests the Board affirm all of the pending claims together.

Thus, in light of the aforementioned reasoning the pending claims have been rejected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of

rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Annette F Dixon/

Examiner, Art Unit 3771

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD HAJEC/

Director, Technology Center 3700

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Janet C. Baxter/
TC 3700 TQAS